



FIG. 5

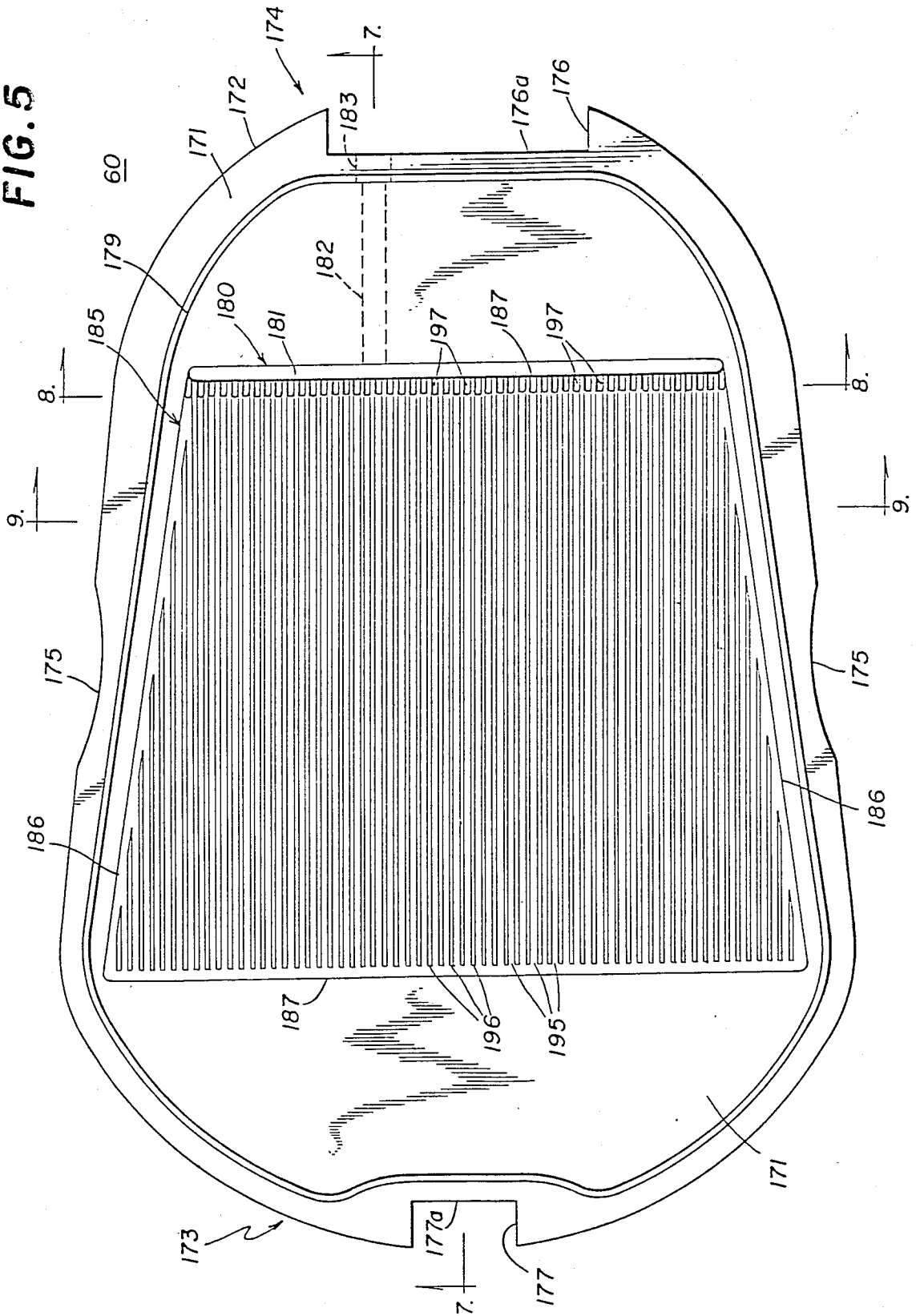
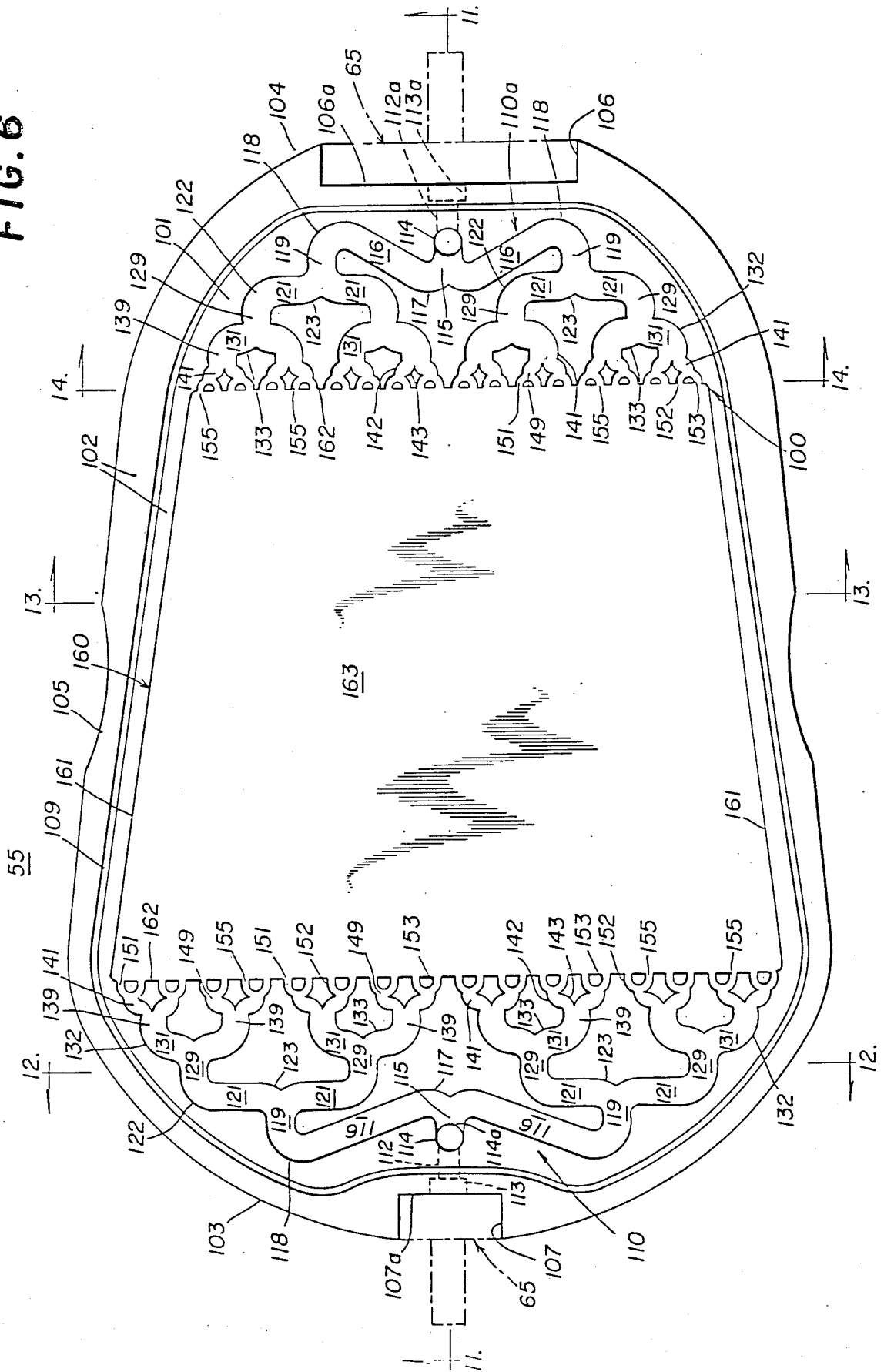


FIG. 6



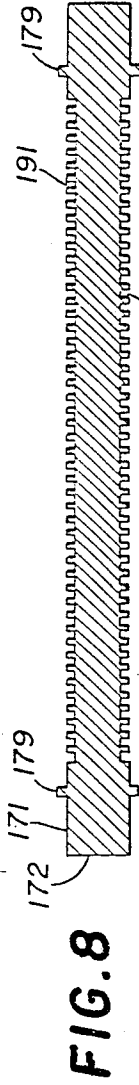
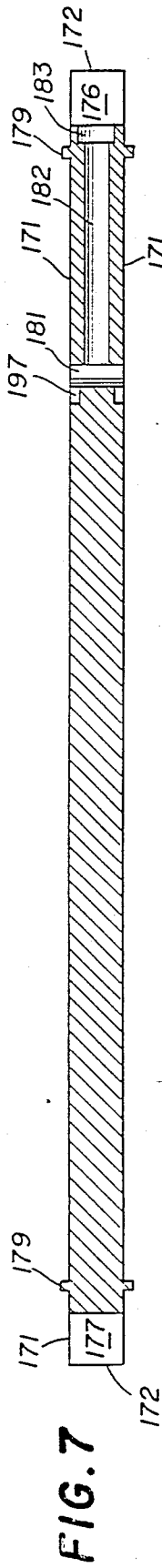


FIG. 9

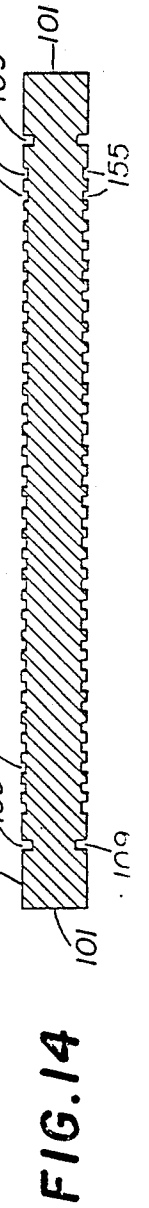
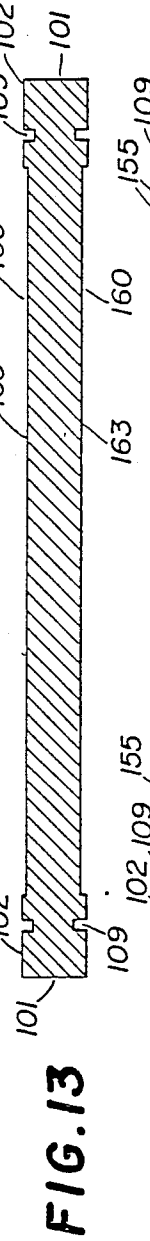
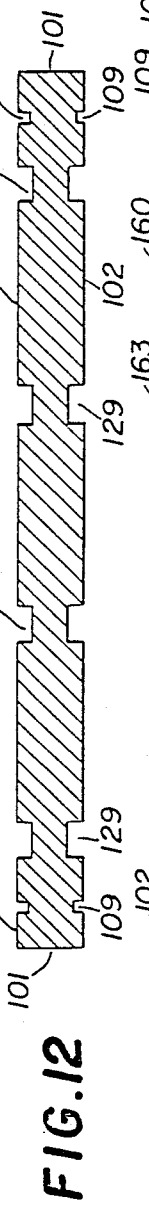
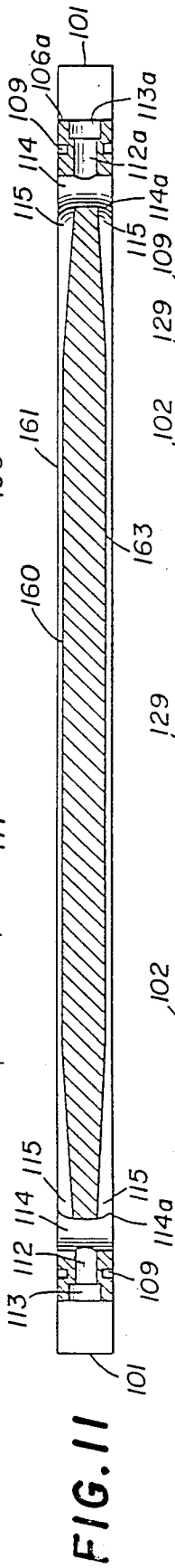
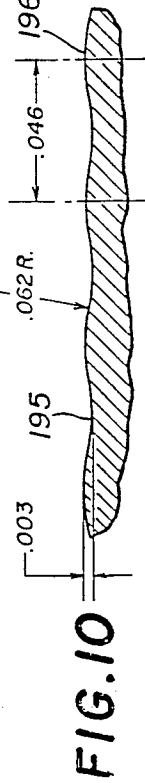
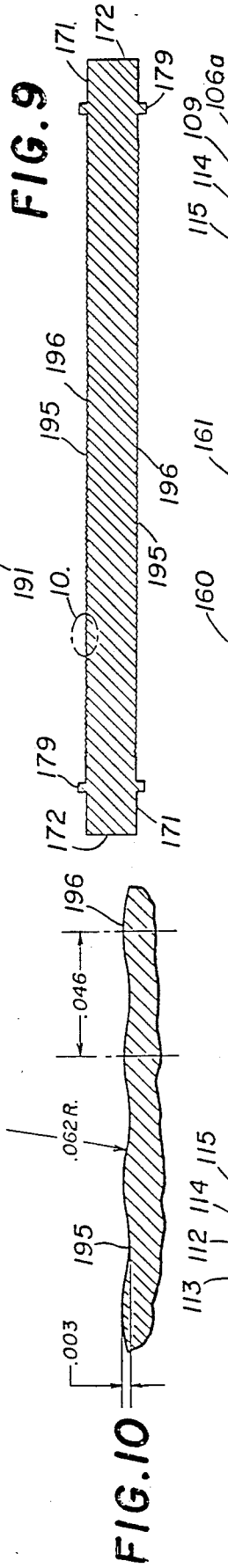




FIG. 20

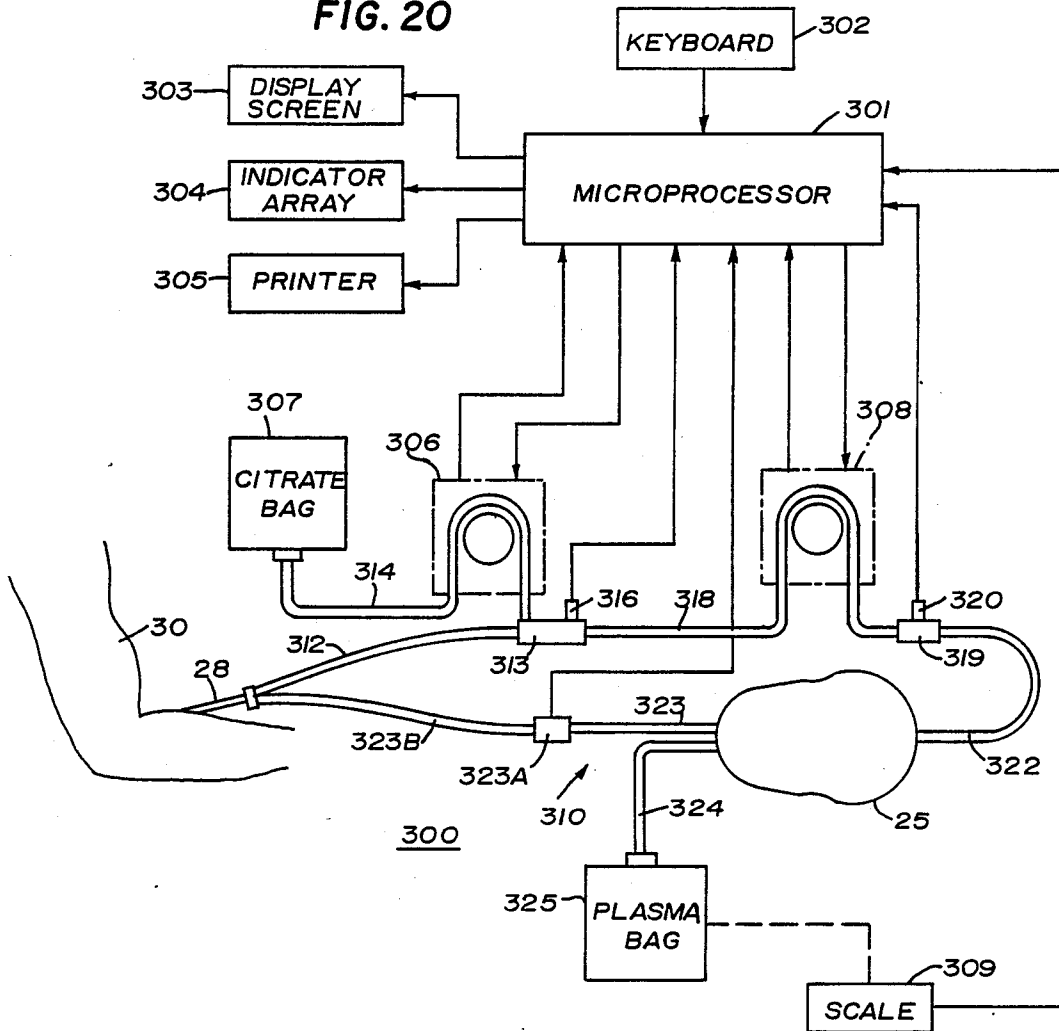


FIG. 24

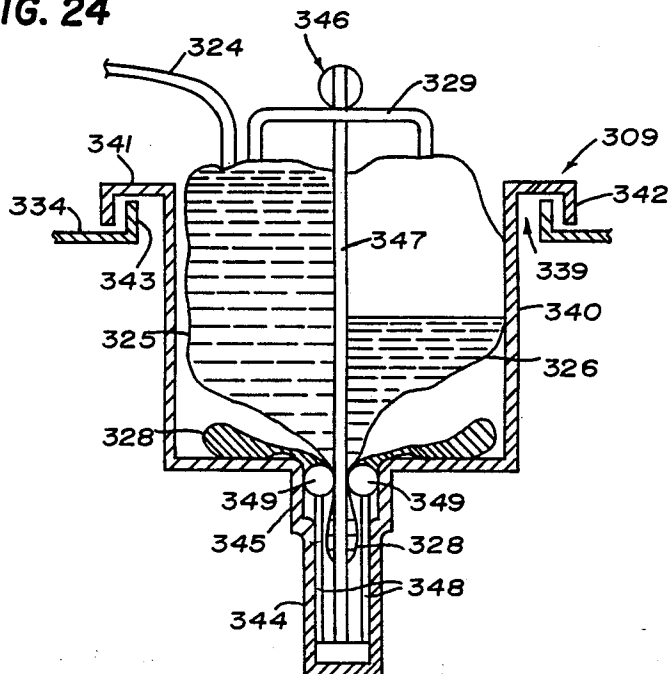
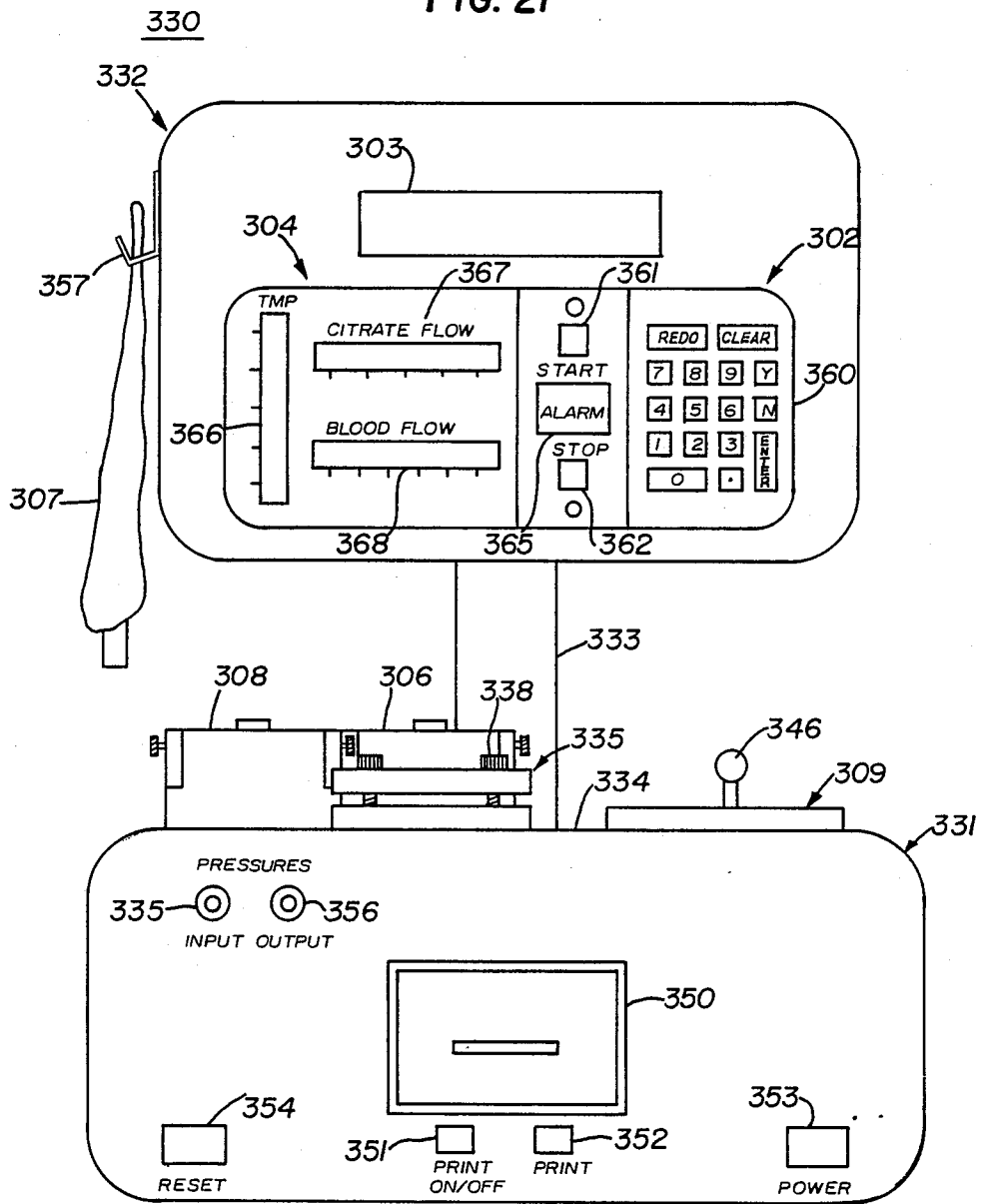


FIG. 21



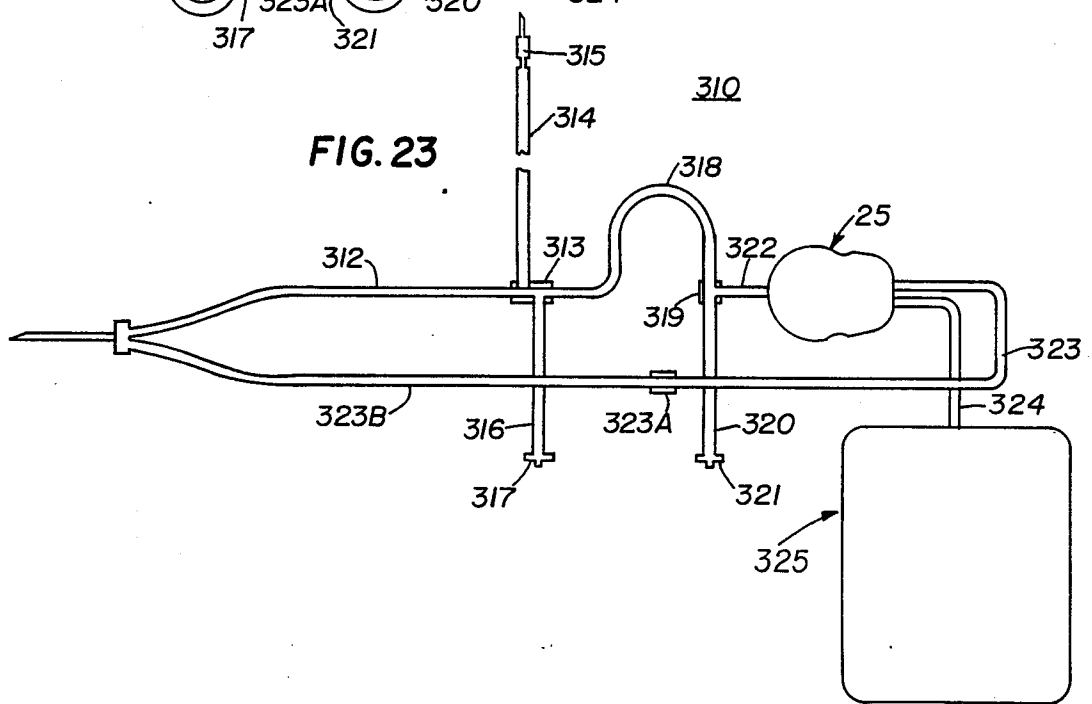
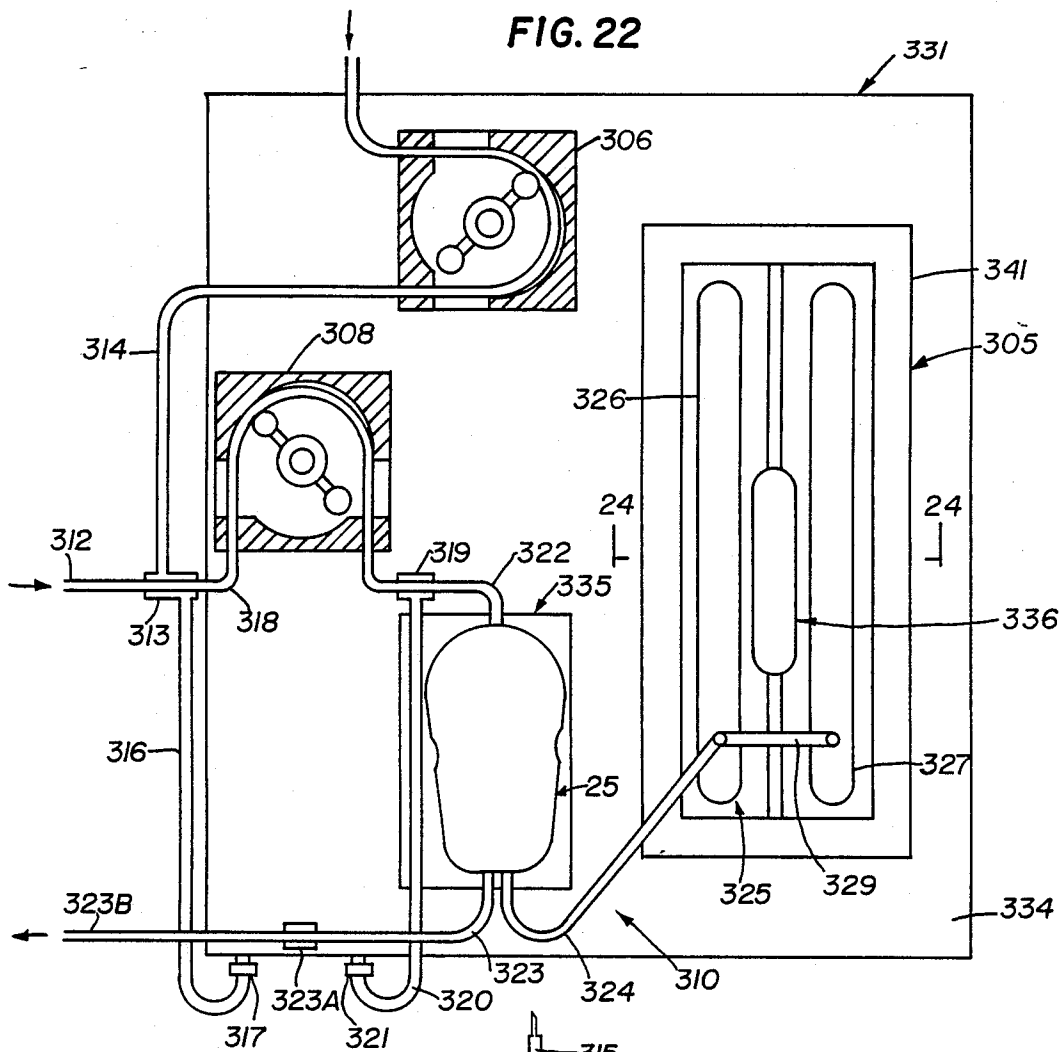


FIG. 25A

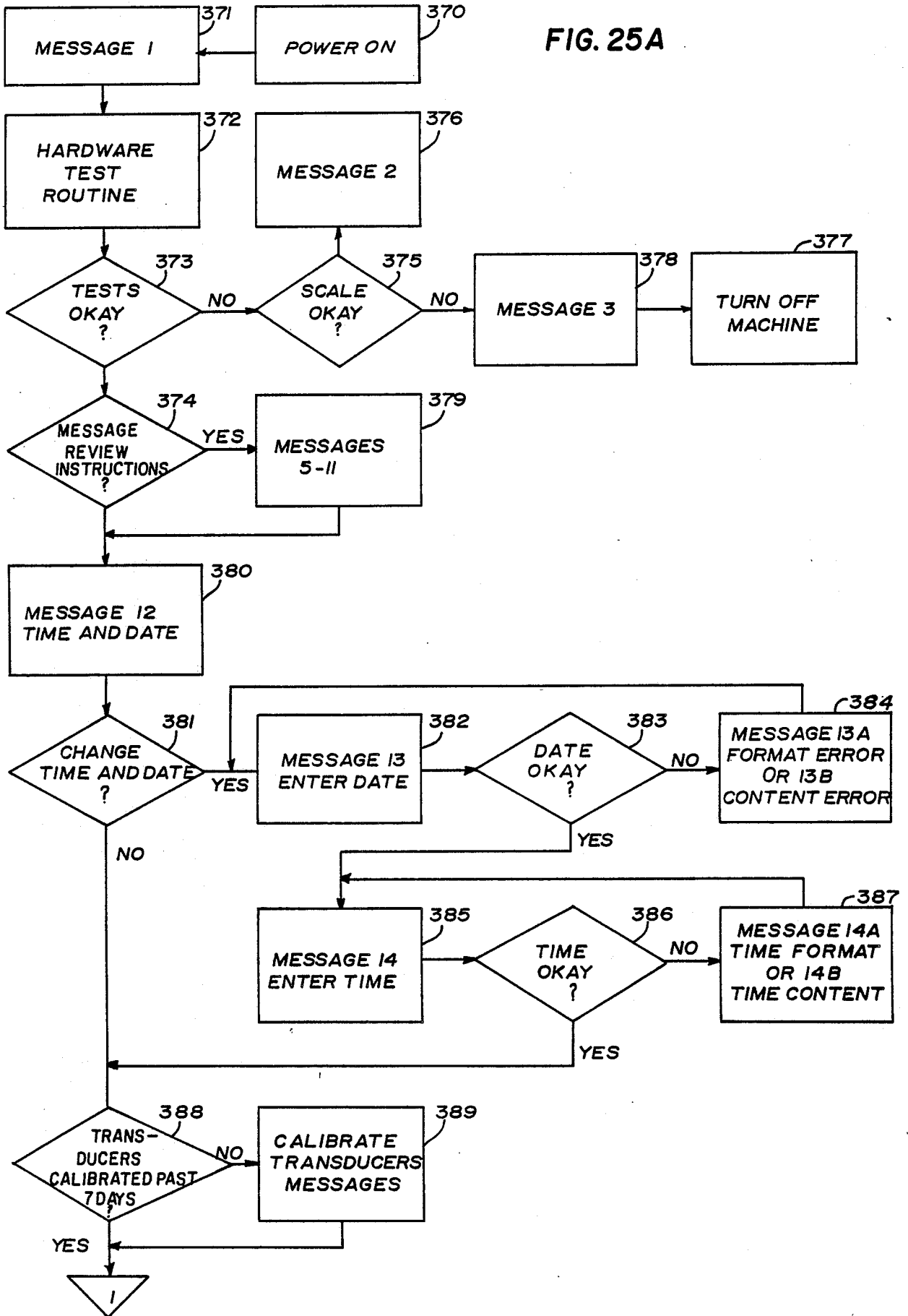


FIG. 25B

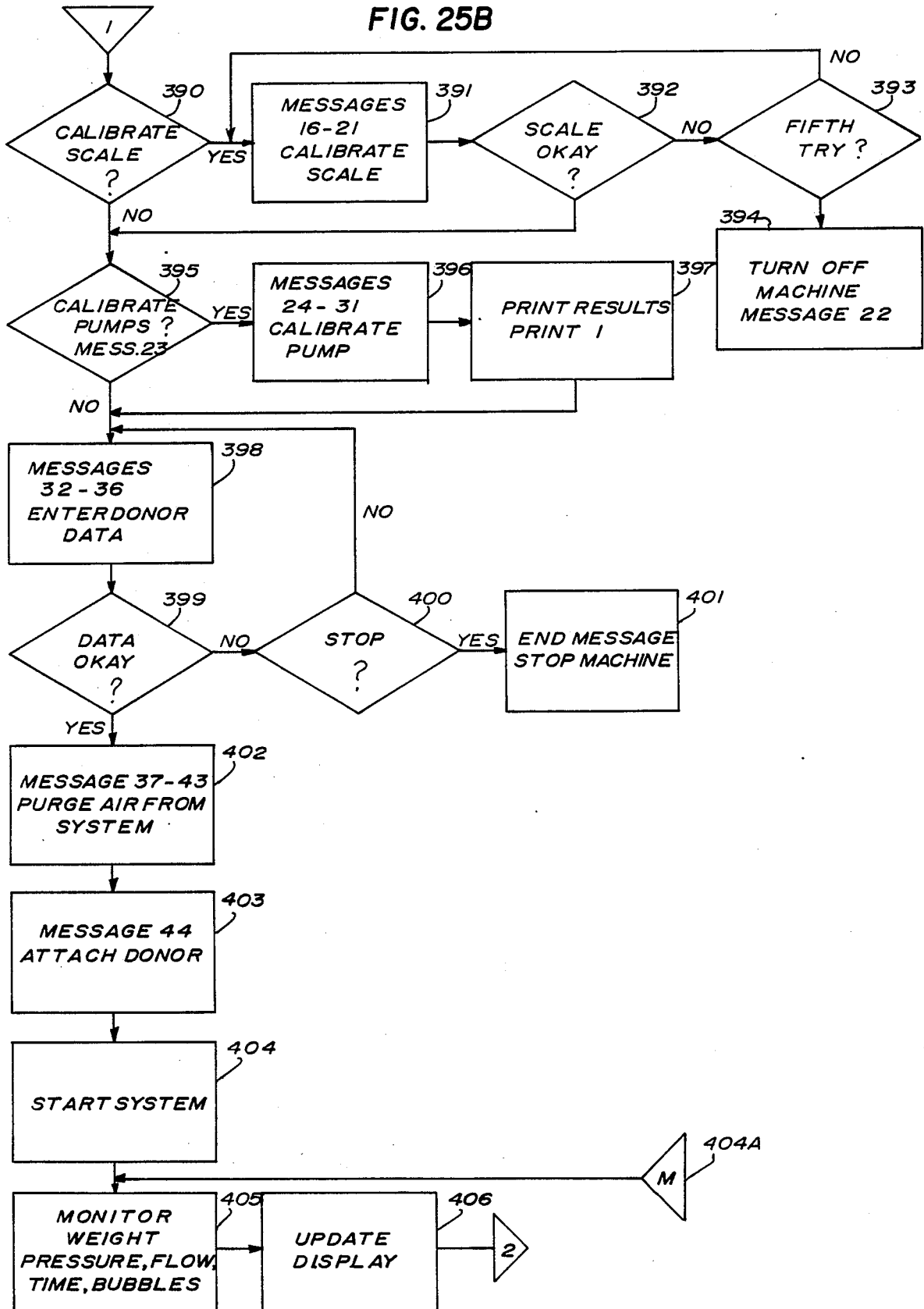


FIG. 25C

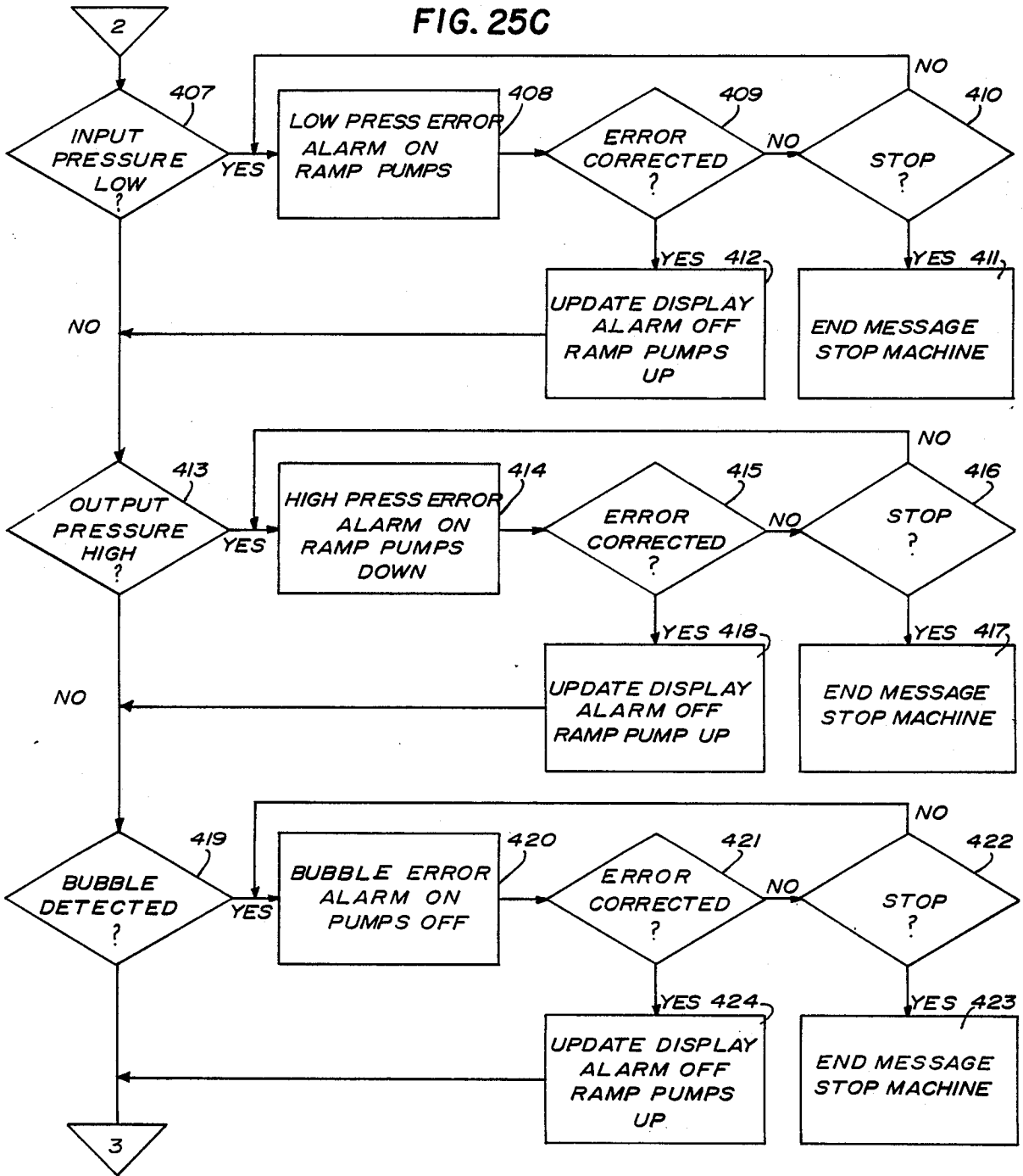
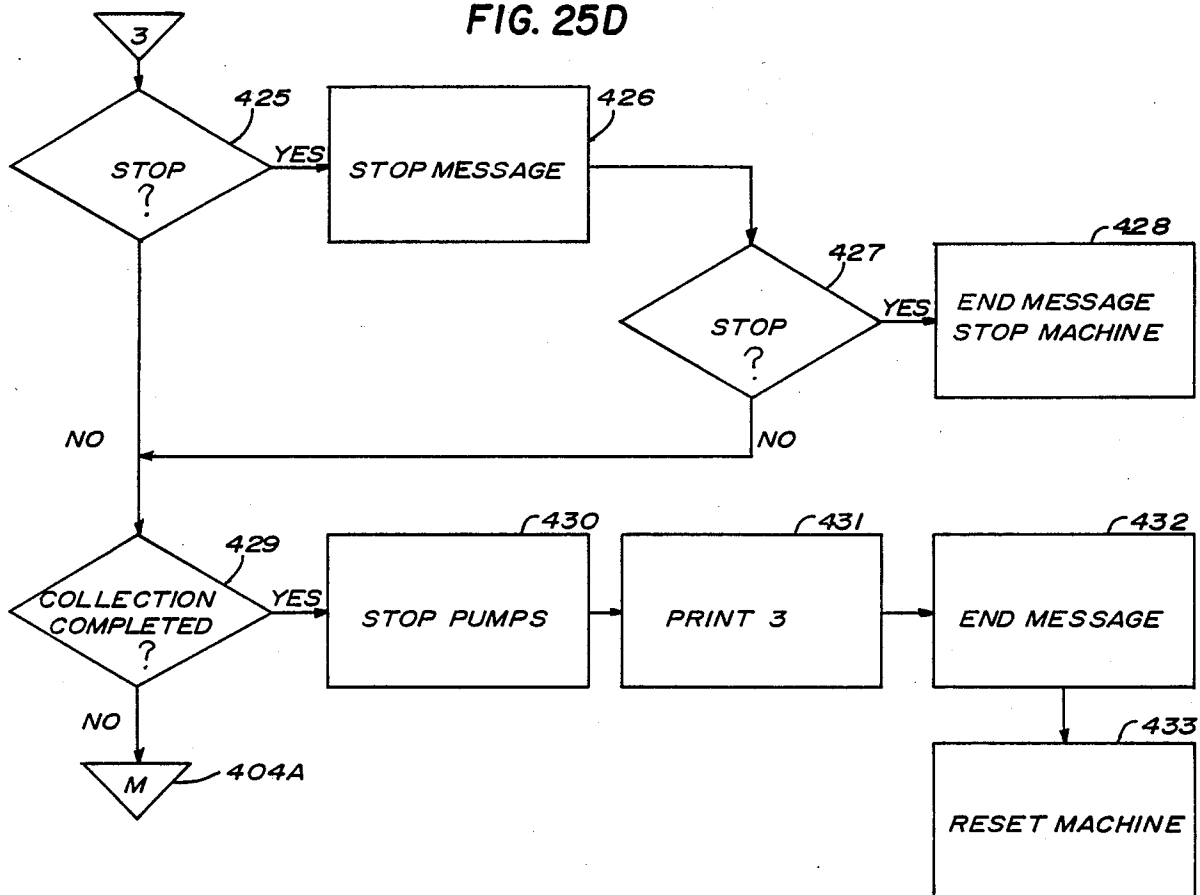


FIG. 25D



SYSTEM AND METHOD FOR CONTINUOUSLY FRACTIONATING BLOOD IN SITU

CROSS REFERENCE TO RELATED APPLICATION

This is a continuation-in-part of copending application Ser. No. 523,007, filed Aug. 15, 1983.

BACKGROUND OF THE INVENTION

The present invention relates to the collection of blood, and in particular, to the fractionating of blood to collect blood substances, such as plasma, cells, or some specific constituent of blood. There are many reasons for fractionating blood to separate various components thereof, one of the most important being to obtain plasma. Plasma has been found to be efficacious in the treatment of various disease states and is generally useful since it may be stored for long periods in comparison to whole blood which has a rather short shelf life.

When harvesting plasma from a donor, it is preferred to return the formed elements of the blood, including red blood cells, white blood cells and platelets, to the donor so that frequent plasma harvestings may be effected. Traditionally, plasma is harvested by transferring blood from a donor into a blood bag containing a fixed amount of anticoagulant solution and thereafter centrifuging the blood to separate the plasma from the formed elements of the blood. The formed elements are thereafter reconstituted with a saline solution and reintroduced to the donor. For a variety of reasons, generally each donor must undergo two such operations for each plasma donation.

The traditional manner of harvesting plasma involves several risks and discomforts to the donor. A principal risk is the chance that the reconstituted blood returned to the donor will not be the donor's, a situation which may result in fatalities. Other attendant risks are those of infection and the like. The discomfort involves, among other things, the inordinate length of time required to permit two samples of blood to be taken with the required centrifuging of each sample, the large volume of blood removed for processing, the reconstituting of the formed elements into a saline solution and reintroducing same to the donor. It is clear that a simpler, safer, speedier system for harvesting plasma is needed and has been needed for a considerable length of time.

One such proposed alternative to the above-described traditional method of harvesting plasma is described in the Blatt et al. U.S. Pat. No. 3,705,100 issued Dec. 5, 1972, which patent discloses an apparatus and method for harvesting plasma from whole blood which includes a cylinder having a reservoir and on the bottom of the cylinder a spiral flow path formed by a spiral groove which sits on top of a membrane having a predetermined pore size. Blood in the reservoir is forced through the spiral path by means of a pressurized gas driving fluid. A second embodiment of the apparatus is disclosed in which a hypodermic syringe is used to withdraw blood from a patient and thereafter introduce the blood into the same sort of spiral flow path as previously described.

The Blatt et al. apparatus and process is not utilized for the commercial production of plasma. The Blatt et al. process and method is, like the described prior art, a batch process and requires withdrawing blood from a donor, treating it and thereafter reintroducing the blood into the donor with all the attendant risks and time

delays previously described. Accordingly, none of the serious drawbacks of the prior art have been solved by the Blatt et al. disclosure.

Another disadvantage of existing plasma harvesting techniques is that neither the amount of plasma collected nor the amount of anticoagulant added thereto is tailored to the individual donor. It is known that the total circulating plasma volume and plasma concentration in a human donor vary as a functions of body weight and hematocrit (red blood cell concentration). In general, the plasma volume varies directly with body weight. For example, plasma volume averages approximately 0.05 liters per kilogram of body weight or about 22.7 ml. per pound of body weight. Thus, plasma volume in a 150 lb. man is approximately 3.4 liters. Plasma concentration varies inversely with hematocrit. Thus, e.g., in a one liter donation with a hematocrit of 45%, the plasma concentration will be 55% or 550 ml.

Body weight of most donors may vary from 110 to 300 lbs., and it has been found that hematocrit varies from about 38% to about 54%. It would be impractical and prohibitively expensive to have different size blood bags and different amounts of anticoagulant to accommodate all the possible variations of body weight and hematocrit values in donors. Consequently, current government guidelines specify two classes of donors, viz., those having a body weight of 174 lbs. or less and those having a body weight over 174 lbs. Current regulations also specify a maximum volume of blood, not plasma, which can be extracted per donor episode. The maximum blood volume is 1 liter per session in a donor of 174 lbs. or less and 1200 ml. per session in a donor of greater than 174 lbs. Since hematocrit varies from 38% to 54%, plasma harvested will vary from 460 to 620 mls. in a 1 liter donation. Therefore, it can be seen that, under current government guidelines, the volume of plasma harvested in a single donor episode as a percent of the total circulating plasma in the donor can vary over a fairly wide range.

Taking the example of a 150 lb. man, having about 3.4 liters of circulating plasma, a one liter whole blood donation may represent anywhere from 13.5% to 18.2% of the donor's initial circulating plasma, depending upon the donor's hematocrit value. It is generally accepted that the maximum percentage of total circulating plasma which safely can be donated in a single episode is 18%. Data collected from actual plasmapheresis at a number of donor centers indicate that the percent of total circulating plasma volume removed ranged from 10% to 22.8% and the percent of total circulating blood volume removed ranged from 4.7% to 14.1%, with small donors giving disproportionately larger amounts of plasma than large donors. Therefore, it is apparent that under current procedures, the plasma harvested from many large donors is considerably less than the maximum safe amount, and that harvested from many small donors is in excess of the maximum safe amount.

Additionally, under current government regulations, one unit of anticoagulant is added to every ten units of collected whole blood. Typically, the anticoagulant is added to the blood bag before collection of the blood. Thus, for example, a blood bag for collecting 500 mls. of whole blood from a person 174 lbs. or less would contain 50 ml. of anticoagulant, while a blood bag for collecting 600 ml. of whole blood from a donor over 174 lbs. would contain 60 ml. of anticoagulant.













































